SonoScape Company Limited

K132527 Page 1 of 10 510(k) Submission

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned	510(k) number:	
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1. Date of submission: August 07, 2013

NOV 1 4 2013

### 2. Submitter

SonoScape Company Limited

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Contact Person: Toki Wu

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#### 3. Proposed Device Identification

Trade/Proprietary Name: S30 Digital Color Doppler Ultrasound System

Common Name: Diagnostic Ultrasound System and Transducers

Classification:

21 FR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 FR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

Classification Panel: Radiology

Device Class: II

### 4. Legally Marketed Predicate Device

SonoScape Company Limited, Diagnostic Ultrasound System, Model SSI-8000 has been cleared by FDA through 510(k) No.K102642 (Decision Date – March 04, 2011).

#### 5. Device Description

The SonoScape S30 Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

### 6. Intended Use Statement

The SonoScape S30 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Trans-esoph (Cardiac), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.

#### 7. Testing

Laboratory testing was conducted to verify that the S30 system with added transducer met all design specification and was substantially equivalent to the Predicate Device. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. The acoustic output is measured and calculated per "NEMA UID 2: 2004 Acoustic Output

Measurement Standard for Diagnostic Ultrasound Equipment" and "NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment".

IEC 60601-1: 2005 Medical Electrical Equipment - Part 1: General Requirements for Safety

IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

IEC 60601-2-37: 2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.

NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

### 8. Clinical Test:

No clinical testing was required.

monitoring equipment.

### 9. Comparison Table

The differences between the S30 and the predicate device SSI-8000 in almost every part are listed in the tables below.

**Table 1 Intended Use Comparison** 

ID	Items	Proposed Device SonoScape S30	Predicate Device SonoScape SSI-8000	Remark
1	Intended Use	The SonoScape S30 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal,	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal,	Same

Trans-esoph (Cardiac),	Trans-esoph (Cardiac),
Peripheral Vascular,	Peripheral Vascular,
Musculo-skeletal	Musculo-skeletal
(Conventional and Superficial	), (Conventional and Superficial),
Cardiac (neonatal and adult),	Cardiac (neonatal and adult),
Urology and OB/Gyn.	Urology and OB/Gyn.

### Table 2 General Comparison

ID	Comparison	Proposed Device	Predicate Device	Remark
טו	Items	SonoScape S30	SonoScape SSI-8000	Remark
2	Classification Name	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Same
3	Product Code	90-IYN/90-IYO/90-ITX	90-IYN/90-IYO/90-ITX	Same
4	Regulation Number	892.1550/892.1560/892.1570	892.1550/892.1560/892.1570	Same
5	Panel	Radiology	Radiology	Same
6	Class	11	l II	Same
7	Probe Type & Connectors	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz L752 Linear Array, 5.0-12.0 MHz 10L1 Linear Array, 6.0-12.0 MHz C362 Curved Array, 2.0-6.0 MHz C344 Curved Array, 2.0-5.0 MHz C353 Curved Array, 2.0-6.0 MHz C542 Curved Array, 2.0-7.0 MHz C322 Curved Array, 2.0-6.0 MHz	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz  C362 Curved Array, 2.0-6.0 MHz C344 Curved Array, 2.0-5.0 MHz	SE Analysis 1

ID	Comparison Items	Proposed Device SonoScape S30	Predicate Device SonoScape SSI-8000	Remark
		MHz C611 Micro-curved Array, 4.0-8.0 MHz C311 Micro-curved Array, 2.0-4.0 MHz	C611 Micro-curved Array, 4.0-8.0 MHz	
		VC6-2 Curved Array, 2.0-6.0 MHz	VC6-2 Curved Array, 2.0-6.0 MHz	
		6V1 Micro-curved Array, 4.0-8.0 MHz	6V1 Micro-curved Array, 4.0-8.0 MHz	
		6V3 Micro-curved Array, 5.0-9.0 MHz EC9-5 Micro-curved Array, 5.0-9.0 MHz BCC9-5 Micro-convex Array	6V3 Micro-curved Array, 5.0-9.0 MHz EC9-5 Micro-curved Array, 5.0-9.0 MHz	
		5.0-9.0MHz BCL10-5 Micro-convex Array 5.0-10.0MHz	·	
		2P1 Phased Array, 2.0-4.0 MHz 5P1 Phased Array, 4.0-7.0 MHz	2P1 Phased Array, 2.0-4.0 MHz 5P1 Phased Array, 4.0-7.0 MHz	
		MPTEE Multi-plane Array, 4.0-7.0 MHz MPTEE mini Multi-plane Array, 4.0-7.0 MHz	MPTEE Multi-plane Array, 4.0-7.0 MHz MPTEE mini Multi-plane Array, 4.0-7.0 MHz	
		Multi-port connector connects 4 transducers	Multi-port connector connects 4 transducers	Same
8	Acoustic Track	TRACK 3	TRACK 3	Same

**Table 3 Functions Comparison** 

D	Comparison	Proposed Device	Predicate Device	Remark	
ַ טיי	Items	SonoScape S30	SonoScape SSI-8000	Remark	
		Based on an embedded Linux	Based on an embedded Linux	Same	
		operating system.  Based on a 64 channel full	operating system.		
		digital beam former.	Based on a 64 channel full digital beam former.	SE	
		Autocorrelation for color	<u> </u>		
		processing and FFT for pulse	Autocorrelation for color processing and FFT for pulse	Same	
		and CW Doppler processing.	and CW Doppler processing.	Carrie	
		Supporting Linear, Curve linear	Supporting Linear, Curve linear		
		and Phase array probes from 2	and Phase array probes from 2	Same	
9	Design	to 15 MHz.	to 15 MHz.		
		Cine play back capability	Cine play back capability	Same	
		Image file archive	Image file archive	Same	
	1	Software upgrade with USB	Software upgrade with USB	Same	
		flash drive.	flash drive.	00.,,0	
		Digital Scan Converter	Digital Scan Converter	Same	
	,	800×600	800×600	<u> </u>	
		With touch panel	With full keyboard	SE Analysis	
				2	
		TGC 8 slider	TGC 8 slider	Same	
		Depth Range: 3 to 32 cm	Depth Range: 3 to 32 cm	Same	
		Image sector size: 32 lines to	Image sector size: 32 lines to	SE Analysis	
		full B (512 lines)	full B (256 lines)	3	
:		Image Sector position: Steering	Image Sector position: Steering	Same	
		within full maximum	within full maximum	Saille	
		B orientation flip :L/R key with	B orientation flip :L/R key with	Same	
		marking on the screen	marking on the screen		
	0	B Dynamic range control:	B Dynamic range control:	Same	
10	Operation Controls	preset 14 curves over 140 dB Gray Scale Control: 7 Settings	Gray Scale Control: 7 Settings	Same	
	Controls			SE	
		Focal Number: 12 focal zone	Focal Number: 9 focal zone	Analysis	
		setting	setting	3	
		B persistence: 0-95%	B persistence: 0-95%	Same	
		Image Processing: Smoothing,	Image Processing: Smoothing.	Same	
		edge enhancement	edge enhancement		
		PW sweeping speed 2,4,6,8	PW sweeping speed 2,4.6,8	Same	
		sec over display	sec over display		
		PW Wall filter setting:16	PW Wall filter setting:16	Same	
L		settings,25 to 750 HZ	settings,25 to 750 HZ		

[ID]	Comparison	Proposed Device	Predicate Device	Remark	
ID	Items	SonoScape S30	SonoScape SSI-8000	ACHIGIR	
		PW sample volume:0.5 to	PW sample volume:0.5 to	Same	
		20mm	20mm	Jaille	
	PW/B update: with UPDATE key		PW/B update: with UPDATE	Same	
			key	Jaine	
		PW cursor steering: Steer soft	PW cursor steering: Steer soft	Same	
	1:	key	key		
		PW angle correction:0 to 80	PW angle correction:0 to 72	SE	
		degree user control	degree user control	Analysis 3	
		PW trace: Peak, Mean	PW trace: Peak, Mean		
		PW spectrum dynamic	PW spectrum dynamic		
		range:10 preset curve over 15-48 dB	range:10 preset curve over 15-48 dB	Same	
	·	Spectrum baseline shift and invert	Spectrum baseline shift and invert	Same	
		Color ROI setting: trackball and set key to control size and position	Color ROI setting: trackball and set key to control size and position	Same	
		Color steering on flat probe:±20, ±16,0	Color steering on flat probe:±20, ±16, 0	Same	
		Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF	Color Wall Filter: Color wall filter with 16 selection,25-750 of PRF	Same	
		Color priority-B priority soft menu	Color priority-B priority soft menu	Same	
		Color Packet size: preset per Exam, horizontal, vertical, off	Color Packet size: preset per Exam, horizontal, vertical, off	Same	
		Zoom adjustable	Zoom adjustable	Same	
		Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Same	
		Cine control: step, play backward, play continuously	Cine control: step, play backward, play continuously	Same	
11	Operation	B. M. PW. CW. CFM, DPI. TDI, Tissue Harmonic Image	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image	Same	
	Mode	3D/4D Mode Color M Mode	3D/4D Mode Color M Mode	_	
12	Display	Dual B, Quad Display, B and M, B and Doppler B + Color, Dual B(Flow)	Dual B, Quad Display, B and M, B and Doppler B + Color, Dual B(Flow)	Same	
	Modes	Triplex mode: B,CFM, and PW/CW; B,DPI, and	Triplex mode: B,CFM, and PW/CW; B,DPI, and	*	

DI	Comparison Items	Proposed Device SonoScape S30	Predicate Device SonoScape SSI-8000	Remark
		PW/CW;B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging.	PW/CW,B,THI and Color M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging.	
13	Measurement Items	Distance; area; circumference; calipers; volume, velocity, HR, PI, RI. Cardiac. OB/GYN, Urology, Vascular and small part package	Distance; area; circumference; calipers; volume, velocity, HR. PI, RI. Cardiac. OB/GYN, Urology, Vascular and small part package	Same
14	Cine Loop	Automatic review/ manual review	Automatic review/ manual review	Same
		Review speed can be adjusted	Review speed can be adjust	Same

### **Table 4 Specifications Comparison**

ID	Comparison Items		Proposed Device SonoScape S30			edicate Device Scape SSI-8	-	Remark
	Power	Voltage: 11	0-127/220-24	0 VAC	Voltage:10	0/220VAC		SE
15		Frequency	: 50/60 Hz		Frequency	: 50/60 Hz		Analysis
	Supply	Power Cor	sumption: 450	OVA	Power Cor	sumption: 33	0 VA	4
	Operating	Temperatu	re: 10~40°C		Temperatu	re: 10~40°C		Same
16	Condition		umidity: 30~75		Relative hu	umidity: 30~7	5%	Same
	Condition	Air pressur	re: 700hPa ~1	060hPa	Air pressur	e: 700hPa ~1	1060hPa	Same
	Storage	Temperatu	re: -20~55°C		Temperatu	re: -20~55℃		Same
17	Condition	Relative hu	umidity: 20~90	)%	Relative hu	ımidity: 20~9	0%	Same
	Condition	Air pressur	Air pressure: 700hPa ~1060hPa		Air pressur	e: 700hPa ~1	1060hPa	Same
18	Screen Size	19 inch Widescreen LCD monitor			17 inch LCD color monitor			SE Analysis 5
		Parameter	Value range	Error range	Parameter	Value range	Error range	
19	Measurement	Display depth	Max 32.9 cm; (Probe depend)	±3%	Display depth	Max 32.9cm; (Probe depend)	±3%	Same
19	Accuracy	Distance	0~31.0 cm	±3%	Distance	0~31.0cm	±3%	Same
		Area	Max. ≥855 cm²	±7%	Area(Tra ce)	Max. ≥855cm²	±7%	Same
		Angle	10~193°	±3%	Angle	10°~193° (Probe depend)	±3%	Same

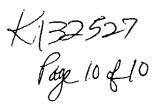
Œ	Comparison Items		Proposed Device SonoScape S30				Remark	
		Circumfe rence	200 cm	±3%	Circumfer ence	200 cm	±3%	Same
		Volume	Max. 25000 cm <sup>3</sup>	±10%	Volume	Max. 25000 cm <sup>3</sup>	±10%	Same
		M-Mode time	2,4,6,8 S	±1%	M-Mode time	2, 4, 6, 8\$	±1%	Same
		Heart Rate	8 ~ 1000 beats/sec	±3%	Heart Rate	8 ~ 1000 beats/sec	±3%	Same
		Slope	1300 cm/s	±3%	Slope	1300 cm/s	±3%	Same
		Velocity (PW)	0.04-2940 cm/s	Angle ≤60°, ≤5%	Velocity( pw)	0.04-2940 cm/s	Angle≤ 60°,≤5 %	Same
		Velocity (CW)	0.12-3795 cm/s	Angle ≤60°, ≤5%	Velocity(c w)	0.13-3529 cm/s	Angle≤ 60°,≤5 %	SE Anahaia
		Velocity (Color)	1-298 cm/s	Angle ≤60°, ≤5%	Velocity (color)	2-226cm/s	Angle≤ 60°,≤5 %	Analysis 6
20	Acoustic Output	Track 3:MI,TIS,TIC,TIB Derated ispta: 720Mw/cm² maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm² max		·		um, laximum,	Same	

### SE Analysis 1:

Probe Type. Compare to the predicate device, the proposed device is with different probe type or frequency, such as L752, 10L1, C353 etc. But no new intended use is added and all of them comply with IEC 60601-2-37, therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

### SE Analysis 2:

The proposed device is with touch panel and the predicate device is with the full keyboard, but both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.



510(k) Submission

#### SE Analysis 3:

The proposed device and the predicate device are with different Image sector size/ Focal number/ PW angle correction, but the proposed device is better. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

### SE Analysis 4

The Power Supply of the proposed device and the predicate device are 110-127/220-240 VAC, 450VA and 100/220VAC, 330 VA respectively, but both of them comply with IEC60601-1 and IEC 60601-1-2. Therefore, power supply can be considered Substantially Equivalent in safety and effectiveness.

#### SE Analysis 5

The screen size of the proposed is larger than that of the SSI-8000. This difference is considered to have no effect on effectiveness and safety.

### SE Analysis 6:

The proposed device and the predicate device are with different measurement accuracy in Velocity (CW/ Color), but the proposed device is better. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

#### Discussion of Substantially Equivalent

The subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device. The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

### 10. Substantially Equivalent Conclusion .

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S30 Digital Color Doppler Ultrasound System is substantially equivalent to predicate devices with regard to safety and effectiveness.





Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

November 14, 2013

SonoScape Company Limited % Ms Toki Wu Regulatory Affairs Manager Yizhe Building, Yuquan Road, Nanshan Shenzhen, Guangdong CHINA 518051

Re: K132527

Trade/Device Name: S30 Digital Color Doppler Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: 11

Product Code: IYN, IYO, and ITX

Dated: August 7, 2013 Received: August 19, 2013

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers, intended for use with the S30 Digital Color Doppler Ultrasound System, as described in your premarket notification:

### Transducer Model Number

2P1 Phase Array	5P1 Phase Array	C611 Micro-curved Array
C311 Micro-curved Array	6V1 Micro-curved Array	6V3 Micro-curved Array
EC9-5 Micro-curved Array	BCC9-5 Micro-curved Array	BCL10-5 Biplane Array
C344 Curved Array	C353 Curved Array	C542 Curved Array
C362 Curved Array	C322 Curved Array	VC6-2 Curved Array
L741 Linear Array	L742 Linear Array	L743 Linear Array
L752 Linear Array	10L1 Linear Array	MPTEE Multi-plane Array
MPTEE mini Multi-plane Array		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations. Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>.

Sincerely yours,

for

Janine M. Morris
Director. Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number:

K132527

Device Name:

\$30 Digital Color Doppler Ultrasound System

Indications for Use: The SonoScape S30 device is a general-purpose ultrasonic

imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Trans-esoph (Cardiac), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac

(neonatal and adult), Urology and OB/Gyn.

Prescription Use	_X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 S	ubpart D)		(21 CFR 807 Subpart C)
•			
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Concurrence of C	DRH, Office	of In Vitro Diagr	nostics and Radiological Health (OIR)
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5	510(k)	K132527	<u> </u>

System:

SonoScape S30

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Мо	de c	of Opera	tion				Öd
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
	Fetal	7	Z	Z		N _	N_	Note 1	Notes 2,4.
	Abdominal	7	Z	2		N	N	Note 1	Notes 2,4.
	Intra-operative Specify								
	Intra-operative Neuro							<u> </u>	ļ
	Laparoscopic								11 11 10 1
	Pediatric	N	N	N		<u>N</u>	N	Note 1	Notes 2,4
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2.4.0
	Neonatal Cephalic	N	Ν	N	N	N	N	Note 1	Notes 2,3,4
Fetal	Adult Cephalic	N	N	N_	N	.N	N	Note 1	Notes 2,3
Imaging&	Trans-rectal	N	Ν	N		N	N	Note 1	Notes 2,4
Other	Trans-vaginal	Ν	7	N	<u> </u>	N	N	Note 1	Notes 2,4
	Trans-urethral				]				ļ
	Trans-esoph.(non-Card)	l		[		<u> </u>	<u> </u>		
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2.4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2.4
	Intravascular		<u> </u>		<u> </u>		<u> </u>		ļ <del></del>
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4
	.Other (Urology)	N	N	N	<u> </u>	N	N	Note 1	Notes 2.
	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2.3
	Cardiac Pediatric	N	N	N	N N	N_	N	Note 1	Notes 2,3
<b>A</b> "	Intravascular(Cardiac)				<u> </u>				ļ
Cardiac	Trans-esoph.(Cardiac)	N	N	N	N	N	N	Note 1	Notes 2,3
	Intra-cardiac		1					<u> </u>	<u> </u>
	Other (specify)	Γ					<u> </u>		<u> </u>
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2.
Vessel	Other (specify)	1	T						

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents); M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

	(Division Sign Off)
	Division of Radiological Health
	Office of In Vitro Diagnostic and Radiological Health
	510(k)
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7-2

Transducer: 2P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application					Mode	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CW	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								<u> </u>
Imaging&	Abdominal	P	Р	Р		P	Р	Note 1	Notes 2,4
Other	Intra-operative Specify	Ι_						<u> </u>	
	Intra-operative Neuro					<u>_</u>			
	Laparoscopic					<u> </u>			
	Pediatric		_				<u> </u>		
	Small Organ (specify)								
	Neonatal Cephalic	P	Р	Ρ	Р	Р	Р	Note 1	Notes 2,3,4
	Adult Cephalic	Р	Р	Р	Ρ_	Р	Р	Note 1	Notes 2,3,4
	Trans-rectal		Ī						
	Trans-vaginal		<u> </u>						<u> </u>
	Trans-urethral	$\perp$							
	Trans-esoph.(non-Card)	Τ							<u> </u>
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular	1							
	Other (Ob/GYN)								
	Other (Urology)	1				T			<u> </u>
Cardiac	Cardiac Adult	P	P	Ρ	P	P	Р	Note 1	Notes 2,3,4
	Cardiac Pediatric	Р	P	Р	Ρ	Р	P	Note 1	Notes 2.3.4
	Intravascular(Cardiac)	1			Ţ			<u> </u>	
	Trans-esoph.(Cardiac)	<b>T</b>						<u> </u>	
•	Intra-cardiac	T			] .				
	Other (specify)		1						
Peripheral	Peripheral vessel		Г						1
Vessel	Other (specify)	1	T					_	_l <u></u>

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contra	st agents)
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: 5P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	ical Application	Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude ) Doppler	Other* Combined	Other* Specify	
Ophthalmic	Ophthalmic									
Fetal	Fetal									
Imaging&	Abdominal					T .				
Other	Intra-operative Specify									
	Intra-operative Neuro			_						
	Laparoscopic	1 -		_						
	Pediatric	P	Р	Р		P	P	Note 1	Notes 2,4	
	Small Organ (specify)	1								
	Neonatal Cephalic	P	Р	P	Р	Р	Ρ .	Note 1	Notes 2,3,4	
	Adult Cephalic	1								
	Trans-rectal	$\top$	Ĭ							
	Trans-vaginal	1								
	Trans-urethral		Ι.							
	Trans-esoph(non-Card)						_			
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Intravascular	1	1							
	Other (Ob/GYN)									
	Other (Urology)	1						<u> </u>	<u></u>	
Cardiac	Cardiac Adult								ļ	
	Cardiac Pediatric	P	P	Р	P	P	P	Note 1	Notes 2,3,4	
	Intravascular(Cardiac)									
	Trans-esoph.(Cardiac)							<u> </u>		
	Intra-cardiac							ļ	<u> </u>	
	Other (specify)						<u> </u>			
Peripheral	Peripheral vessel				ļ					
Vessel	Other (specify)					_[	dded under	<u> </u>	<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents)
THE PARTY OF THE P
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD
WINCOID WI, DICOID DOPPIER, DICOID DOPPIEM TES, SIT THE STEPPIEM TE

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: C611 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clin	nical Application	1	Mode of Operation  Color Power Other Other								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude ) Doppler	Other* Combined	Specify		
Ophthalmic	Ophthalmic							ļ			
Fetal	Fetal								<u></u> ,		
lmaging&	Abdominal	Р	Р	Р		Ρ	Р	Note 1	Notes 2.4		
Other	Intra-operative Specify										
	Intra-operative Neuro	T									
	Laparoscopic										
	Pediatric	ΤP	Р	Р		P	Р	Note 1	Notes 2,4		
	Small Organ (specify)	Ī		Ī							
	Neonatal Cephalic	P	P	Р	Р	Р	P	Note 1	Notes 2,3,4		
-	Adult Cephalic	T									
	Trans-rectal	Т			_						
	Trans-vaginal		Ĭ								
	Trans-urethral	1		<u> </u>							
	Trans-esoph(non-Card)							<u> </u>			
	Musculo-skeletal						İ				
	(Conventional)		<u> </u>			<u> </u>		ļ			
	Musculo-skeletal	1									
	(Superficial)	1				<u> </u>		<u> </u>			
	Intravascular			_	<u> </u>	<u> </u>		<u> </u>			
	Other (Ob/GYN)	┷	<u> </u>					Ļ	<u></u>		
_	Other (Urology)		<u> </u>								
Cardiac	Cardiac Adult		<u> </u>	<u> </u>	<u> </u>			<u> </u>			
	Cardiac Pediatric	P	P	Р	P	Р	P	Note 1	Notes 2,3,4		
-	Intravascular(Cardiac)		<u> </u>								
	Trans-esoph.(Cardiac)			<b>⊥</b>		<u> </u>			<b>_</b>		
	Intra-cardiac		$\perp$	↓	L.—						
	Other (specify)			<u> </u>	<u> </u>			<u> </u>			
Peripheral	Peripheral vessel				ļ			<u> </u>			
Vessel	Other (specify)	Ţ ¯			<u> </u>			1	<u> </u>		

N = new indication:	P = previoush	y cleared by FDA;	E = added	under this appendix
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Note 1: Other Comb	ined includes:	B/M; B/PWD;	B/THI (The fe	eature does not	use contrast age	nts);
				Power Dopple		

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: C311 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	ical Application	Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude ) Doppler	Other* Combined	Other* Specify	
Ophthalmic	Ophthalmic									
Fetal	Fetal	1			l					
lmaging&	Abdominal	N	N	N		N _	N	Note 1	Notes 2.4	
Other	Intra-operative Specify	1		<u> </u>						
	Intra-operative Neuro									
	Laparoscopic	Ţ								
	Pediatric						<u></u>			
	Small Organ (specify)				<u> </u>		<u></u>			
	Neonatal Cephalic	T	Π	I						
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4	
	Trans-rectal	T								
	Trans-vaginal						<u></u>			
	Trans-urethral									
	Trans-esoph(non-Card)									
	Musculo-skeletal			i		1				
	(Conventional)		<u> </u>					<b> </b>		
	Musculo-skeletal (Superficial)									
	Intravascular		Т							
•	Other (Ob/GYN)		П	Ī						
	Other (Urology)			T		<u> </u>		<u> </u>		
Cardiac	Cardiac Adult			Π			<u> </u>			
	Cardiac Pediatric	N	Z	N	N	N	N	Note 1	Notes 2,3,4	
	Intravascular(Cardiac)							<u> </u>		
	Trans-esoph.(Cardiac)								ļ	
	Intra-cardiac							<u> </u>	ļ <u> </u>	
	Other (specify)			<u> </u>			<u> </u>	<u> </u>		
Peripheral	Peripheral vessel			<u> </u>			<u> </u>			
Vessel	Other (specify)			l	_	_l	1404	.1	<u> </u>	

renphera:	Leubireigi Aegoei					<del></del>				
Vessel	Other (specify)			<u></u>		<u> </u>				
N = new indication; P = previously cleared by FDA; E = added under this appendix										
Note 1: Oth	er Combined includes:	B/M; B/PWD;	B/THI (The	feature does	not use contra	ist agents);				
M/C	Color M; B/Color Doppl	er; B/Color Do	ppler/PWD	; B/Power Dop	pler/PWD					
Note 2: Tiss	sue Harmonic Imaging									
Note 3: TDI		Note 5: 4	łD							
Note 6: Sm	all Organ: breast, thyro	id, testes								

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7-6

Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify		
Ophthalmic	Ophthalmic										
Fetal	Fetal										
Imaging&	Abdominal										
Other	Intra-operative Specify								<u> </u>		
	Intra-operative Neuro							<u> </u>			
	Laparoscopic							l			
	Pediatric				·						
	Small Organ (specify)							<u> </u>			
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal	P	Р	Р		Р	Р	Note 1	Notes 2.4		
	Trans-vaginal	Р	Р	Р		P	P	Note 1	Notes 2.4		
	Trans-urethral										
	Trans-esoph.(non-Card)										
	Musculo-skeletal										
	(Conventional)	<u> </u>				<u> </u>	<u> </u>				
	Musculo-skeletal										
	(Superficial)				<u> </u>	<u> </u>					
	Intravascular				_						
	Other (Ob/GYN)					<u> </u>					
	Other (Urology)	Р	Р	Р		Р	Р	Note 1	Notes 2.4		
Cardiac	Cardiac Adult				[						
	Cardiac Pediatric					L					
	Intravascular(Cardiac)					L					
	Trans-esoph.(Cardiac)						<u> </u>				
	Intra-cardiac								<u> </u>		
	Other (specify)										
Peripheral Peripheral vessel					<u> </u>	<u> </u>					
Vessel	Other (specify)				I	L		<u> </u>	<u>                                     </u>		

N = new indication;	P = previously	y cleared by FDA;	E = added	under this appendix
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Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents	5)
M/Color M: B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application	Mode of Operation							
General	Specific	<u> </u>				Color	Power	Other*	Other*
(TRACK 1 ONLY)	(TRACKS 1 & 3)	В	М	PWD	CWD	Doppler	(Amplitude) Doppler	Combined	Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal	Γ							
Imaging&	Abdominal	Γ							
Other	Intra-operative Specify	]		,					
	Intra-operative Neuro								
	Laparoscopic	Ţ			Ĭ				
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic							_	
	Adult Cephalic	1							
	Trans-rectal	Р	Р	P		Р	Р	Note 1	Notes 2,4
	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2.4
	Trans-urethral	1							
	Trans-esoph (non-Card)								
	Musculo-skeletal	1	T -						
	(Conventional)				İ			ļ. <u>.</u>	
	Musculo-skeletal	Г	Ţ		Γ				
	(Superficial)	<u> </u>						<u> </u>	
	Intravascular				<u> </u>	<u></u>		_	
	Other (Ob/GYN)	L				<u> </u>	<u> </u>		
	Other (Urology)	Ρ	P	Р	<u>l</u>	P	Р	Note 1	Notes 2.4
Cardiac	Cardiac Adult					<u> </u>		<u> </u>	
	Cardiac Pediatric								
	Intravascular(Cardiac)		Ι					ļ	
	Trans-esoph.(Cardiac)								
	Intra-cardiac							<u> </u>	
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)	1		J				<u> </u>	<u>]</u>

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1:	Other Combined includes:	B/M; B/PWD; B/THI	(The feature does	not use contrast a	agents);
	M/Color M: B/Color Dopol	er: R/Color Dopoler/F	2M/D: B/Power Doc	inler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: EC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application	Mode of Operation  Color Power Other*							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								
Fetal Imaging&	Abdominal	T							
Other	Intra-operative Specify				]				
	Intra-operative Neuro	T						-	
	Laparoscopic	1							
	Pediatric	1							
	Small Organ (specify)								
	Neonatal Cephalic	1							
	Adult Cephalic	1							
	Trans-rectal	N	N	z		N	N	Note 1	Notes 2.4
	Trans-vaginal	N	N	Z		N	N	Note 1	Notes 2.4
	Trans-urethral	1-							
	Trans-esoph.(non-Card)	1	T						
	Musculo-skeletal								
	(Conventional)								
	Musculo-skeletal	1							
	(Superficial)		ļ						
•	Intravascular								<u></u>
	Other (Ob/GYN)								
	Other (Urology)	N	N	N	Ţ	N <sub>.</sub>	N	Note 1	Notes 2.4
Cardiac	Cardiac Adult	1	1						
	Cardiac Pediatric				-	1			
	Intravascular(Cardiac)				1				
	Trans-esoph.(Cardiac)	1							
	Intra-cardiac								
	Other (specify)	1	1 _		]				
Peripheral	Peripheral vessel	1	1						
Vessel	Other (specify)	$\top$	1						

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast ag	ents)
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: BCC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal							<u></u>	
Imaging& Other	Abdominal	[				<u> </u>			ļ
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic	-							
	Pediatric								
	Small Organ (specify)	T						<u> </u>	
	Neonatal Cephalic		Г <u> </u>						
	Adult Cephalic							<u> </u>	
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral	Г							
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)						-		
	Musculo-skeletal (Superficial)								
	Intravascular				<u> </u>				
	Other (Ob/GYN)					1	Ĩ		, _
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph (Cardiac)	T -							<u> </u>
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel		Τ						
Vessel	Other (specify)	1		T				1	

N = new indication:	P = previously cleared	I by FDA:	E = added u	nder this app	pendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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7-10

Transducer: BCL10-5 Biplane Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Ctir	ical Application	Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								
Imaging& Other	Abdominal	Γ							
	Intra-operative Specify								
	Intra-operative Neuro				<u> </u>				
	Laparoscopic					<u> </u>			
	Pediatric	Γ				<u> </u>			
	Small Organ (specify)	Ī							
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2.4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2.4
	Trans-urethral	T							<u> </u>
	Trans-esoph.(non-Card)				T				
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular	$\top$			1				<u> </u>
	Other (Ob/GYN)	1							
	Other (Urology)	N	N	N		N	Ν	Note 1	Notes 2.4
Cardiac	Cardiac Adult	1	$\top$		]				<u> </u>
	Cardiac Pediatric	1						<u> </u>	
	Intravascular(Cardiac)				I			<u> </u>	
	Trans-esoph.(Cardiac)	1						<u> </u>	
	Intra-cardiac								<u> </u>
	Other (specify)							<u> </u>	<del></del>
Peripheral	Peripheral vessel								
Vessel	Other (specify)	Т		,			ided under 1	<u></u>	

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application	Mode of Operation								
General	Specific	<del>                                     </del>				Color	Power	Other*	Other*	
(TRACK 1 ONLY)	(TRACKS 1 & 3)	В	M	PWD	CWD	Doppler	(Amplitude) Doppler	Combined	Specify	
Ophthalmic	Ophthalmic	Ī								
Fetal	Fetal	P	Р	₽.		Р	ρ	Note 1	Notes 2.4	
lmaging&	Abdominal	P	₽	Р		Р	P	Note 1	Notes 2.4	
Other	Intra-operative Specify									
	Intra-operative Neuro									
	Laparoscopic									
	Pediatric									
	Small Organ (specify)	Π								
	Neonatal Cephalic									
	Adult Cephalic		$\Box$							
	Trans-rectal	1	1							
	Trans-vaginal	1								
	Trans-urethral	T_		1						
	Trans-esoph.(non-Card)	1								
	Musculo-skeletal					ſ	-			
	(Conventional)							<u> </u>		
	Musculo-skeletal					-				
	(Superficial)		<u> </u>							
	Intravascular									
	Other (Ob/GYN)	Р	P	P		Р	Р	Note 1	Notes 2.	
	Other (Urology)	ΙP	Р	Р		Р	Р	Note 1	Notes 2.	
Cardiac	Cardiac Adult	П	Ι							
	Cardiac Pediatric						[			
	Intravascular(Cardiac)				Ĭ					
	Trans-esoph.(Cardiac)								L	
	Intra-cardiac								<u> </u>	
	Other (specify)									
Peripheral	Peripheral vessel							<u></u>		
Vessel	Other (specify)				[					

N = new indication; P = previo	usly cleared by FDA;	E = added under this appendix
Note 1: Other Combined includes:	B/M; B/PWD; B/THI (TI	he feature does not use contrast agents);
M/Color M; B/Color Dopple	er; B/Color Doppler/PW	D; B/Power Doppler/PWD
Note 2: Tissue Harmonic Imaging		
Note 3: TDI Note 4: 3D	Note 5: 4D	

Note 3: TDI Note 4: 3D Note 5: 4 Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-12

Transducer: C353 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application	$T^{-}$					Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	8	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other <sup>a</sup> Combined	Other* Specify
Ophthalmic	Ophthalmic .			_					
Fetal	Fetal	N	2	N		N	N	Note 1	Notes 2,4
Imaging&	Abdominal	N	z	N		N _	N	Note 1	Notes 2,4
Other	Intra-operative Specify						<u></u>		
	Intra-operative Neuro							<u> </u>	
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								<u> </u>
	Neonatal Cephalic								ļ
	Adult Cephalic						<u> </u>		
	Trans-rectal	1							ļ
	Trans-vaginal			ļ					
	Trans-urethral								
	Trans-esoph.(non-Card)	i –							
	Musculo-skeletal		]	1		İ			
	(Conventional)								
	Musculo-skeletal						]		
	(Superficial)						<u></u>		
	Intravascular		l					ļ <u>.                                    </u>	<u> </u>
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4
	Other (Urology)	N	N	N	<u> </u>	N	N	Note 1	Notes 2.4
Cardiac	Cardiac Adult			<u> </u>				ļ <u> </u>	
	Cardiac Pediatric							ļ	
	Intravascular(Cardiac)	Ė		L	<u> </u>			<u> </u>	ļ
	Trans-esoph (Cardiac)							<u> </u>	<b>↓</b>
	Intra-cardiac			1				<u> </u>	<u> </u>
	Other (specify)							<u> </u>	ļ
Peripheral	Peripheral vessel								ļ.   .
Vessel	Other (specify)				1	<u> </u>	dded under 1	<u></u>	<u></u>

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use	contrast agents);
M/Color M: B/Color Doppler: B/Color Doppler/PWD: B/Power Doppler/PV	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: C542 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	Mode of Operation								
General Specific						Color	Power	Other*	Other*
(TRACK 1 ONLY)	(TRACKS 1 & 3)	В	M	PWD	CWD	Doppler	(Amplitude) Doppler	Combined	Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								
lmaging&	Abdominal	N	N	N		N	N	Note 1	Notes 2.4
Other	Intra-operative Specify	1				_			
	Intra-operative Neuro								
	Laparoscopic	Ī							
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)								<u> </u>
	Neonatal Cephalic								
	Adult Cephalic								<u> </u>
	Trans-rectal	T			Ī				
	Trans-vaginal								
	Trans-urethral	1							
	Trans-esoph.(non-Card)								<u> </u>
	Musculo-skeletal								
	(Conventional)	ł	i						
	Musculo-skeletal	Ī							
	(Superficial)								
	Intravascular	Τ_	}		<u> </u>				<u> </u>
	Other (Ob/GYN)	$\Box$							
	Other (Urology)	Ñ	N	N	<u> </u>	N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult			_					<u> </u>
	Cardiac Pediatric	T	T						<u> </u>
	Intravascular(Cardiac)		Τ.		]				
	Trans-esoph.(Cardiac)								<u> </u>
	Intra-cardiac								<u> </u>
	Other (specify)								
Peripheral	Peripheral vessel	7							
Vessel	Other (specify)	T -	T					·	

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agent	(s)
M/Color M: B/Color Doppler: B/Color Doppler/PWD: B/Power Doppler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: C362 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power: (Amplitude) Doppler	Other* Combined	Other* Specify		
Ophthalmic	Ophthalmic	i .									
Felal	Fetal	P	Р	Р		Р	Δ.	Note 1	Notes 2,4		
lmaging&	Abdominal	P	Р	Р		Р	2	Note 1	Notes 2,4		
Other	Intra-operative Specify				<u> </u>						
	Intra-operative Neuro	Ī					_				
	Laparoscopic										
	Pediatric				Γ _			<u></u>			
	Small Organ (specify)						_				
	Neonatal Cephalic										
	Adult Cephalic										
ĺ	Trans-rectal				Ī .						
	Trans-vaginal							<u> </u>			
	Trans-urethral		Ī								
	Trans-esoph.(non-Card)	1		Ī							
	Musculo-skeletal	Ï						1			
	(Conventional)										
	Musculo-skeletal (Superficial)										
	Intravascular	+	┼		<del>†</del>			<b> </b>	<del> </del>		
	Other (Ob/GYN)	P	P	P	+	Р	P	Note 1	Notes 2,4		
	Other (Urology)	P	P	P	<del> </del> -	P	Р	Note 1	Notes 2.4		
Cardiac	Cardiac Adult	+	+	<u> </u>	<del> </del>	<u> </u>		<b> </b>			
Carolic	Cardiac Pediatric	+	$\vdash$			<del>                                     </del>			<u> </u>		
	Intravascular(Cardiac)	+-	t	<del>                                     </del>	†	<del>                                     </del>	· · ·	<del>                                     </del>			
	Trans-esoph (Cardiac)	<del>                                     </del>	†	ļ —	<del>                                     </del>		<del></del>				
	Intra-cardiac	1	† -	<del></del>	1 —	<del>                                     </del>	<del>                                     </del>				
	Other (specify)	†	$t^-$	<del> </del>	<del>                                     </del>	<del>                                     </del>	† <del></del>				
Peripheral	Peripheral vessel	+	1	<del> </del>	1	1		T			
Vessel	Other (specify)	+	1		-	1	1	1			

N = new indication;	P = previous!	y cleared by FDA;	E = added	l under th	is appendix
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Note 1: Of	ther Combined includes:	B/M; B/PWD;	B/THI (The	feature does not	use contrast	agents)
	Color M: B/Color Donal					

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: C322 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic				<u> </u>				
Fetal	Fetal	N	N	N		N	N	Note 1	Notes 2,4
lmaging&	Abdominal	Ñ	N.	N		N	N .	Note 1	Notes 2.4
Other	Intra-operative Specify						<u> </u>		ļ <u></u> .
	Intra-operative Neuro	T			l		<u> </u>		
	Laparoscopic						<u></u>		<u></u>
	Pediatric				<u> </u>				
	Small Organ (specify)						<u> </u>		
	Neonatal Cephalic						<u> </u>		
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								<u> </u>
	Trans-urethral								
	Trans-esoph.(non-Card)	7							
	Musculo-skeletal				ľ				
	(Conventional)			<u> </u>		<u> </u>		_	
	Musculo-skeletal		T						
	(Superficial)				_				ļ <u>.</u>
	Intravascular								ļ. <u>.</u>
	Other (Ob/GYN)	Ν	N	N		N	N	Note 1	Notes 2.4
	Other (Urology)						<u> </u>		<u> </u>
Cardiac	Cardiac Adult								
	Cardiac Pediatric		$I_{-}$	Γ		<u> </u>			
	Intravascular(Cardiac)	Τ	T			<u> </u>	<u> </u>		<u> </u>
	Trans-esoph.(Cardiac)							<u> </u>	<del> </del>
	Intra-cardiac								<u> </u>
	Other (specify)								<b> </b>
Peripheral	Peripheral vessel							<u> </u>	ļ. <u> </u>
Vessel	Other (specify)	T		1			ddod undor		.l

	l					1	:
M = nous in	dication:	P = previously	/ cleared h	IV FIJA:	· ⊢=aoo	iea unaer ti	us abbendix
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Note 1	: Other	Combined in	ncludes: E	B/M; B/PWD;	B/THI (1	The feature of	does not i	use contrast	agents);
		for M: B/Cold							

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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7-16

Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application	T				Mode	of Operation	(	
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal	Р	Ρ	P		P	Р	Note 1	Notes 2,4,5
Imaging &	Abdominal	Р	Ρ	Р		Р	Р	Note 1	Notes 2.4.5
Other	Intra-operative Specify			<u> </u>			<u></u>		
	Intra-operative Neuro							<u> </u>	
	Laparoscopic								
	Pediatric			L.,					l
	Small Organ (specify)		Ĺ			<u></u>			L
	Neonatal Cephalic					_		<u> </u>	
	Adult Cephalic		Ì	L	<u> </u>				
	Trans-rectal			<u> </u>					ļ
	Trans-vaginal					<u> </u>		<u> </u>	
	Trans-urethral						<u> </u>		
	Trans-esoph (non-Card)								
	Musculo-skeletal	T					ļ	İ	
	(Conventional)	<u> </u>	<u> </u>		<u> </u>			ļ	<u> </u>
	Musculo-skeletal (Superficial)								
	Intravascular			[			<u> </u>		ļ
	Other (Ob/GYN)	P	P	P		Р	P	Note 1	Notes 2.4.5
	Other (Urology)	T					<u></u>	<u></u>	<u> </u>
Cardiac	Cardiac Adult	T	1					<u> </u>	
	Cardiac Pediatric	7	Π					<u> </u>	<u> </u>
	Intravascular(Cardiac)	1					<u></u>	1	ļ
	Trans-esoph (Cardiac)								
	Intra-cardiac							ļ	<u> </u>
	Other (specify)								<u> </u>
Peripheral	Peripheral vessel							<u> </u>	
Vessel	Other (specify)						ddad uadar		L

N = new indication;	P = previously cleared by FDA;	E = added dilder tills appendix	
Note 1: Other Combine	ed includes: B/M; B/PWD; B/THI (The	he feature does not use contrast agents	3)
M/Color M; B/	Color Doppler; B/Color Doppler/PW	VD; B/Power Doppler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application	T				Mode o	f Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								
Imaging&	Abdominal					_		_	
Other	Intra-operative Specify								
	Intra-operative Neuro					_		ļ	
	Laparoscopic								
	Pediatric		Γ		_				
	Small Organ (specify)	Ρ	P	Р		Р	P	Note 1	Notes 2,4,6
	Neonatal Cephalic			_				<u> </u>	
	Adult Cephalic								
	Trans-rectal	Ţ							
	Trans-vaginal								
	Trans-urethral				Ĺ		· 	ļ	
	Trans-esoph.(non-Card)	T					<u> </u>		
	Musculo-skeletal (Conventional)	Р	Р	Р	Р	Р	Р	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)								
	Intravascular		1						<u></u>
	Other (Ob/GYN)		1	[	<u> </u>				<u> </u>
	Other (Urology)	1	1						
Cardiac	Cardiac Adult	1	$\top$		T			<u> </u>	
	Cardiac Pediatric	$T^-$			Ι				
	Intravascular(Cardiac)	1							
	Trans-esoph.(Cardiac)	Ĺ					<u> </u>	1	
	Intra-cardiac								ļ
	Other (specify)	1							
Peripheral	Peripheral vessel	P	Р	P		Р	Р	Note 1	Notes 2,4
Vessel	Other (specify)								<u> </u>

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agent	ts)
M/Color M: B/Color Doppler: B/Color Doppler/PWD: B/Power Doppler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application	Mode of Operation								
General Specific		-				Color	Power	Other*	Other*	
(TRACK 1 ONLY)	(TRACKS 1 & 3)	8	M	PWD	CWD	Doppler	(Amplitude) Doppler	Combined	Specify	
Ophthalmic	Ophthalmic							<u> </u>		
Fetal	Fetal									
Imaging&	Abdominal									
Other	Intra-operative Specify	Ι								
	Intra-operative Neuro									
	Laparoscopic							L	l	
	Pediatric									
	Small Organ (specify)	Р	Р	Р		Р	Р	Note 1	Notes 2,4,6	
	Neonatal Cephalic			•						
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal	T	$\Box$							
	Trans-urethral	1	1						<u> </u>	
	Trans-esoph.(non-Card)									
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Note 1	Notes 2,4	
	Musculo-skeletal (Superficial)	Р	Р	P		Р	Р	Note 1	Notes 2.4	
	Intravascular		Γ		ŀ	]				
	Other (Ob/GYN)								<u> </u>	
	Other (Uralogy)	1								
Cardiac	Cardiac Adult							<u> </u>		
	Cardiac Pediatric	Ī	Ι							
	Intravascular(Cardiac)	Ι.			I					
	Trans-esoph.(Cardiac)									
	Intra-cardiac									
	Other (specify)									
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Note 1	Notes 2.4	
Vessel	Other (specify)		[		1				<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contra	ast agents);
M/Color M: B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD	•

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: L743 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application	Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify	
Ophthalmic	Ophthalmic							<u></u>		
Fetal	Fetal					_				
Imaging&	Abdominal									
Other	Intra-operative Specify									
	Intra-operative Neuro			_		_				
	Laparoscopic						_			
	Pediatric							<u> </u>		
	Small Organ (specify)	P	Р	Р		Р	Р	Note 1	Notes 2.4.6	
	Neonatal Cephalic									
	Adult Cephalic	1				<u> </u>				
	Trans-rectal	T								
	Trans-vaginal	П								
	Trans-urethral									
	Trans-esoph.(non-Card)									
	Musculo-skeletal (Conventional)	Р	Р	Р		P	, b	Note 1	Notes 2.4	
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2.4	
	Intravascular	1								
	Other (Ob/GYN)	1								
	Other (Urology)									
Cardiac	Cardiac Adult	1							<u> </u>	
	Cardiac Pediatric	1							I	
	Intravascular(Cardiac)	1				Ī .				
	Trans-esoph (Cardiac)	$\top$	Ī							
	Intra-cardiac	T		]						
	Other (specify)	1	П							
Peripheral	Peripheral vessel	P	P	Р	1	Р	Р	Note 1	Notes 2.4	
Vessel	Other (specify)	1	Т	Ī						

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI	(The feature does not use contrast agents):
M/Color M; B/Color Doppler; B/Color Doppler/F	WD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: L752 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clii	nical Application					Mode o	of Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	M	PWD	CWD	Color Doppier	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								
Imaging&	Abdominal					<u> </u>		<u>                                       </u>	
Other	Intra-operative Specify					_		<u> </u>	
	Intra-operative Neuro						l		
	Laparoscopic				[-				
	Pediatric	1			Ī				<u> </u>
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic	T		Ì					_
	Trans-rectal	1			1				
	Trans-vaginal						Ī		
	Trans-urethral	Ì							
	Trans-esoph (non-Card)		1						
	Musculo-skeletal	N	N	N		N	N	Note 1	Notes 2.4
	(Conventional)		1			l		_	
	Musculo-skeletal	N	N	N		N	N	Note 1	Notes 2,4
	(Superficial)								
	Intravascular		ŀ			_			
	Other (Ob/GYN)								
	Other (Urology)								<u> </u>
Cardiac	Cardiac Adult								
	Cardiac Pediatric					Ĭ			
	Intravascular(Cardiac)								
	Trans-esoph (Cardiac)								
	Intra-cardiac							L	
	Other (specify)		Π						
Peripheral	Peripheral vessel	N	Ν	N		N	N	Note 1	Notes 2,4
Vessel	Other (specify)	Ĭ							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast age	:nts);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 40

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use	

Page 021 of 024

Transducer: 10L1 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Ise: Diagnostic ultrasou nical Application	1	IIIIa	girig Oi	naia no	Mode o	f Operation	500) 05	
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic							<u></u>	
Fetal	Fetal								
Imaging&	Abdominal								
Other	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic				L				
	Pediatric				<u> </u>			ļ <u> </u>	
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic	<u> </u>				<u> </u>		<u> </u>	
	Adult Cephalic				<u> </u>	_			
	Trans-rectal								ļ <u> </u>
	Trans-vaginal				<u> </u>				
	Trans-urethral		Γ		ļ				ļ
	Trans-esoph.(non-Card)					<u> </u>	<u> </u>		L
	Musculo-skeletal (Conventional)	N	N	N	ļ !	N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular	1							<u> </u>
	Other (Ob/GYN)						<u> </u>		
	Other (Urology)	Π	1.					<u>l</u>	
Cardiac	Cardiac Adult	T-	T					<u></u>	<u> </u>
	Cardiac Pediatric	1	1					<u> </u>	
	Intravascular(Cardiac)								<u> </u>
	Trans-esoph.(Cardiac)							<u> </u>	<u> </u>
	Intra-cardiac							<u> </u>	
	Other (specify)								
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
Vessel	Other (specify)					]	ddod undor		.l

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: MPTEE Multi-plane Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clir	nical Application	T	Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify		
Ophthalmic	Ophthalmic										
Fetal	Fetal										
Imaging&	Abdominal										
Other	Intra-operative Specify					<u> </u>			<u>.</u>		
	Intra-operative Neuro	Ţ			_		<u>.                                    </u>				
	Laparoscopic										
	Pediatric							<u> </u>	<u> </u>		
	Small Organ (specify)							<u> </u>	<u> </u>		
	Neonatal Cephalic										
	Adult Cephalic					<u> </u>	<u> </u>				
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph.(non-Card)	[.				<u> </u>					
	Musculo-skeletal	Ţ		· ·				1			
	(Conventional)	<u>l</u>	<u> </u>		<u> </u>				_ <del></del>		
	Musculo-skeletal (Superficial)										
	Intravascular	1									
	Other (Ob/GYN)	1		1		-					
	Other (Urology)										
Cardiac	Cardiac Adult	$\top$									
	Cardiac Pediatric		1								
	Intravascular(Cardiac)	1					<u> </u>				
	Trans-esoph.(Cardiac)	P	P	Þ	1	Р	Р	Note 1	Notes 2,3.4		
	Intra-cardiac	1									
	Other (specify)	1									
Peripheral	Peripheral vessel	1			$\mathbb{L}$						
Vessel	Other (specify)		T								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agent	ts)
M/Color M: B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Transducer: MPTEE mini Multi-plane Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	se: Diagnostic ultrasor		Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	Ν	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify		
Ophthalmic	Ophthalmic										
Fetal	Fetal	Ι.			_						
Imaging&	Abdominal										
Other	Intra-operative Specify	l							<del>_</del>		
	Intra-operative Neuro				L	<u> </u>					
	Laparoscopic						<u> </u>				
	Pediatric				<u> </u>	<u></u>					
	Small Organ (specify)				<u> </u>						
	Neonatal Cephalic	П				_					
	Adult Cephalic		Ī			I		<u> </u>			
	Trans-rectal						•				
	Trans-vaginal							<u></u>			
	Trans-urethral		T -								
	Trans-esoph (non-Card)	1			1						
	Musculo-skeletal	1	1								
	(Conventional)		1		<u> </u>			ļ			
	Musculo-skeletal (Superficial)								<u></u>		
	Intravascular	1									
	Other (Ob/GYN)	<b>†</b> -	1	†							
	Other (Urology)	1	1		1						
Cardiac	Cardiac Adult	1	$\top$		T						
	Cardiac Pediatric		$\vdash$								
	Intravascular(Cardiac)		1					l			
	Trans-esoph (Cardiac)	P	P	Р		Р	Р	Note 1	Notes 2.3.		
	Intra-cardiac		$\Box$				<u> </u>		<u> </u>		
	Other (specify)	1	Τ								
Peripheral	Peripheral vessel								ļ		
Vessel	Other (specify)					1	iddad undar	<u> </u>	<u>.l</u>		

N = new indication: P = pr	eviously cleared by FDA;	E = added t	under this appendix
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Note 1: 0	Other Combined includes:	B/M; B/PWD;	B/THI (The f	eature does	not use contra	st agents):
	M/Color M; B/Color Doppl	er; B/Color Do	ppler/PWD; I	B/Power Dop	pler/PWD	

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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